K060772

OCT 16 2006

H 510(k) Summary – Traditional Submission

510(k) Owner

Establishment:	MedSafe ASA
Address:	Forskningsveien 2A, N-0373 Oslo, Norway
Phone:	+47 23 22 36 14
Fax:	+47 22 14 02 55

Contact Person

Name:	Nils Gunnarsson
Establishment:	MedSafe ASA
Address:	Forskningsveien 2A, N-0373 Oslo, Norway
Phone:	+47 23 22 36 14
Fax:	+47 22 14 02 55

Date of Preparation

March 9, 2006

Identification of the Device

1. Proprietary Name: Manual Safety Syringe (2-parts),
   Manual Safety Syringe (3-parts)
2. Common Name: Sharps Injury Prevention Piston Syringe
3. Classification Name: Antistick Syringe
4. Class II, Procodes: FMF – Piston Syringe
   MEG – Antistick Syringe
   FMI – Hypodermic Single Lumen Needle

Equivalent Legally Marketed Device

Claim of Substantial Equivalence is made to BIOTOP DJT-A Safety Syringe (K032747).

Intended Use

The Manual Safety Syringe is a single-use safety hypodermic syringe for intramuscular and subcutaneous injection of medication to patients. This device aids in prevention of needlestick injuries.

Description of the Device

The Manual Safety Syringe is a single-use safety hypodermic syringe, which is very similar to a traditional syringe, with the exception that it possesses an integral needle retracting mechanism. The device comes in two variations:

3. Manual Safety Syringe (2-parts) 5ml
4. Manual Safety Syringe (3-parts) 5ml

The Manual Safety Syringe (2-parts) consists of a conventional syringe barrel equipped with a mechanism that shall prevent re-use of an already used syringe. When the plunger is pressed in its bottom position the injection is completed. When retracting the plunger the snare will drag the needle into the barrel, and thus prevent reuse of the syringe. The cone prevents the needle from going back into the barrel during the injection. The nozzle holds the needle, snare and cone and is attached to the barrel prior to injection. The needle cap protects the needle when handled. Also, when pulled back, the plunger is unable to be detached from the barrel. As an additional safety feature the operator is encouraged to break off the plunger when the plunger has been pulled back.

The Manual Safety Syringe (3-parts) is identical to the 2-parts version with respect to the operation of the device. The design differs only with respect to the plunger and the lubrication. The 3-parts version is equipped with an extra sealing and the inside of the barrel is lubricated with silicon. The 2-parts version is not lubricated.

The Manual Safety Syringe is only available in one size (5ml).

Safety and Effectiveness, Comparison to Predicate Device

	The Manual Safety Syringe	BIOTOP DJT-A Safety Syringe
Syringe type	Antistick syringe	Antistick syringe
Intended use	The Manual Safety Syringe is a single-use safety hypodermic syringe for intramuscular and subcutaneous injection of medication to patients. This device aids in prevention of needlestick injuries.	Similar
Principle of operation	Activation of safety feature consists of three steps: 1) Press the plunger to the bottom position to complete injection. 2) Retract the plunger to full stop to drag the needle into the barrel. 3) Brake plunger off.	Identical
Volume (ml/cc)	5ml	1ml/3ml/5ml
Nozzle type	Luer	Luer Lock Tip
Barrel		Identical

marking		
Reuse	Non-reusable	Identical
Materials	1. Barrel: Polypropylene	Polypropylene
	2. Plunger: Polyethylene	Polypropylene
	3. Snare Polypropylene	N/A
	4. Needle: Stainless steel	Stainless steel
	5. Cone: Polycarbonate	N/A
	6. Nozzle: Polycarbonate	Polypropylene
	7. Sealing Thermoplastic Elastomer Compound	Unknown
	8. Lubrication Silicon lubrication	Unknown
	9. Needle cap Polypropylene	Unknown
	10. Primary container: Peel-packs made of plastic	Unknown
	11. Secondary container: Cardboard box	Unknown
	12. Transport container: Currogated cardboard	Unknown
Sterility	Sterilized by ethylene oxide gas	Sterilized by ethylene oxide gas
	SAL $\leq 10^{-6}$	SAL = 10^{-6}

Table 10 Table of Comparison

Conclusion

In all material respects, the Manual Safety Syringe is substantially equivalent to the predicate device. The conclusion is based on biocompatibility testing, compliance with voluntary standards, and comparison to the predicate device. A clinical evaluation has been performed and the results show that the Manual Safety Syringe 5ml is clinically acceptable.

End of 510(k) summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 2006

Mr. Jan-Erik Mikkelborg
Managing Director
MedSafe ASA
Forskningsveien 2A
N-0373 Oslo, Norway

Re: K060772
Trade/Device Name: Manual Safety Syringe MS 1178-2 (5ml, 22G, 1 ¼")
Manual Safety Syringe MS 1178-3 (5ml, 22G, 1¼")
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: September 13, 2006
Received: September 18, 2006

Dear Mr. Mikkelborg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

C Indications for Use

510(k) Number (if known): ___K060772___

Device Name: ___Manual Safety Syringe_MS 1178-2 (5 ml, 22G, 1 ¼")_____
___Manual Safety Syringe_MS 1178-3 (5 ml, 22G, 1 ¼")_____

Indications for Use:

The Manual Safety Syringe is a single-use safety hypodermic syringe for intramuscular and subcutaneous injection of medication. This device aids in prevention of needle stick injuries.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Anthony D. Watson 10/16/2006

...gn-Off)
...n of Anesthesiology, General Hospital,
...on Control, Dental Devices

...umber: K060772